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| 10/074,017 | 02/14/2002 | Ishay Ostfeld | OSTFELD1 | 5626 |
| 23117 | 7590 | 05/19/2005 | EXAMINER | |
| NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203 | | | DESANTO, MATTHEW F | |
| | | | ART UNIT | PAPER NUMBER |

3763

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,017

Applicant(s)

OSTFELD ET AL.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 February 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-18,20,21,24-31 and 34 is/are pending in the application.
4a) Of the above claim(s) 15,16,19-24,29,31 and 34 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1,3-14,17,18,25,26 and 30 is/are rejected.
7) ☒ Claim(s) 27, 28 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species B in the reply filed on 2/24/05 is acknowledged. The traversal is on the ground(s) that the species should be patentable distinct. This is not found persuasive because this is not a proper reply to the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 15, 16, 20, 21, 24, 29, 31, and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 2/24/05.

Claim Objections

3. Claim 27 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to the other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

4. Claim 28 is objected to because it depends on a cancelled claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 3,8-11, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Coulter (USPN 5,417,666).

7. Coulter teaches a catheter system with one embodiment teaching an interior cover (5) for a cannula (4) and another embodiment teaches an external cover (15) for a cannula (14). The cover is removed after the device has been inserted in the patient

8. Claims 1,4,8-10,12 and 14, are rejected under 35 U.S.C. 102(b) as being anticipated by Chin (USPN 5,571,172).

Chin teaches a cover for a medical device such as a stent (column 4, line 45) wherein the cover has a row of perforations allowing for easy removal from the device after the system has been inserted into the patient. The perforations on the cover create a rough surface.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 5-7, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coulter in view of another embodiment of Coulter.

Coulter teaches two separate embodiments, one having a cover on the interior of the medical device and the other a cover on the exterior of the device. In both embodiments, the cover is removed after the device is inserted in the body.

It would have been obvious to one skilled in the art at the time of the invention to incorporate the use of both covers at the same time in order to keep all surfaces of the device sterile as well as to vary the composition of the material to enhance the specific characteristics of the medical device depending on the medical procedure being performed.

11. Claims 17, 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coulter in view of Maloney et al. (USPN 5,188,606)

Coulter, as described above, teaches a cover for a medical device that is removed after the device is inserted into the patient, but fails to teach a blade that splits the cover in order to remove it from the surface of the device.

Maloney et al. teaches a slitter comprising a blade used to slit an introducer for removal from a catheter.

It would have been obvious to one skilled in the art at the time of the invention to incorporate this slitter for removal means of the protective cover for the catheter system instead of having to manufacture a cover with a preformed slit.

Claims 14, 25, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coulter in view of Holman et al.

Coutler, as described above, teaches a cover for a medical device that is removed after the device is inserted into the patient, but fails to teach a ring at the distal end of the shaft as well as different specific characteristics drawn to the cover.

Holman et al as described above teaches a cover for a stent, and further teaches a ring (120) as the distal end of the shaft. [0113]

It would have been obvious to one skilled in the art at the time of the invention to provide such a device in order to prevent material from entering between the cover and the surface. That the cover is impenetrable to water and microorganisms further protects the sterility of the device

Allowable Subject Matter

12. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

13. Applicant's arguments filed 8/05/04 have been fully considered but they are not persuasive.

14. The applicant argues that Coutler does not disclose a medical device and that the device of Coutler is not a catheter or cannula. According to claim 1 the medical device can be a catheter or drain or cannula. The device of Coutler is used as a catheter or cannula because fluid is capable of passing through it. Also the device of Coutler is being used in a medical procedure and therefore the device would be a medical device. The device of Coutler is capable of being used as a catheter or

cannula since it comprises the same structure as a catheter or cannula. The examiner would also like to note that because the prior art and the applicant's invention are different, the language in the claim must be patentable distinct, which is not the case here. Therefore, the examiner keeps his rejection in view of Coutler.

15. The applicant argues that Chin doesn't disclose a cover for a medical device. Once again the examiner takes the stance that any device being used in a medical procedure is a medical device and that the detachable covers of Chin fall within the scope of the claimed invention, as well as that Chin is capable of being used as a catheter, which is a medical device. Therefore, the examiner holds his rejection.

16. The applicant argues the same concepts with regards to the other rejections, and therefore, directs the applicants attention to the above two paragraphs.

The examiner would also like to note that in order for an apparatus claim to be patentable disclose, there should be some structure that is claimed and is not taught or suggested by the prior art. Claim 13 would be allowable if it was rewritten in independent form and included all of the limitations of the base claim and any intervening claims

Conclusion


17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.


Matthew DeSanto
Art Unit 3763
May 16, 2005


NICHOLAS D. LUCCHESI
SUPERVISOR PATENT EXAMINER
TECHNOLOGY CENTER 3700